

IN THE UNITED STATES PATENT AND TRADEMARK OFFICEApplicant: **Keith D. ALLEN**Serial No.: **10/045,624**Filed: **October 26, 2001**Title: **Transgenic Mice Containing Thyroid
Stimulating Hormone Receptor (TSH-R)
Gene Disruptions**Group Art Unit: **1632**Examiner: **Paras Jr., Peter**Customer No. **26619**Docket/Order No. **R-666**Date: **July 2, 2003**RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Mail Stop Non-Fee Amendment
P.O. Box 1450
Arlington VA 22313-1450

Sir:

In response to the Office Action mailed June 3, 2003, concerning the Examiner's restrictions, Applicant hereby provisionally elects, with traverse, Invention III (claims 5-6, 12-38 and 40), drawn to a transgenic non-human animal, particularly a mouse comprising a disruption in a TSH-R gene, and a method of making the same.

In the restriction, the Examiner asserts that claims 1-42 are drawn to seven distinct subjects, grouped as: Invention I (claim 1), drawn to a targeting construct comprising nucleotide sequences homologous to a TSH-R gene; Invention II (claims 2-4, 7 and 39), drawn to cells comprising a disruption in a TSH-R gene; Invention III (claims 5-6, 12-38 and 40), drawn to a transgenic non-human animal, particularly a mouse comprising a disruption in a TSH-R gene, and a method of making the same; Invention IV (claim 8), drawn to methods of identifying agents that modulate the expression of a TSH-R gene or modulate the function of a TSH-R comprising screening said agents in a transgenic non-human animal; Invention V (claims 9-10), drawn to methods of identifying agents that modulate expression of a TSH-R gene or function of a TSH-R in a cell *in vitro*; Invention VI (claims 11 and 41), drawn to unknown agents; and Invention VII (claim 42), drawn to an agonist or antagonist of a TSH receptor. Applicant respectfully traverses the requirement for restriction and request reconsideration and withdrawal of the requirement.

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As stated in MPEP §803, the requirements for a proper claim restriction are as follows: “(a) the inventions must be independent or distinct as claimed; and (b) there must be a serious burden on the examiner if restriction is required.”

A proper claim restriction must place a “serious burden” on the Examiner if the claims were examined without a restriction. In order to establish a serious burden, the Examiner must “show by appropriate explanation one of the following: separate classification thereof, a separate status in the art, or a different field of search.” This showing of a serious burden is required even if the claimed inventions have been shown to be distinct. See MPEP §808.02

The instant Office Action generally asserts that restriction is warranted between Inventions I through VII in that the claimed inventions are patentably distinct. The Examiner has based this conclusion on alleged material (biological, chemical or functional) differences between compositions, or alleged differences in the materials and modes of operation required for methods. However, Applicant submits that the Examiner has not established that a serious burden would result from a search of the invention groups together. Applicant does not believe that the Examiner has fulfilled the requirements for a proper claim restriction based on a serious burden standard. Applicant believes that a search of any one of Invention groups I through VII would produce results that would encompass the subject matter of each of the invention groups. Thus, a serious burden would not be placed on the Examiner in order to conduct a search and examination of the claims of Inventions I through VII.

Specifically, the Examiner asserts that the claims of Inventions I, II, III, VI and VII are distinct each from the other in that they have different modes of operation, different function, and different effects. More particularly, the Examiner states that the products of the Inventions have different chemical structures, are made by different methods, and can be used in different methods which require different technical considerations and materially different reagents. The Applicant disagrees that restriction is proper, in that the products of these inventions are related. Further, a search or examination of the prior art related to one of the invention groups, *e.g.* transgenic animals comprising TSH-R gene disruptions, would produce results encompassing each of the invention groups. Therefore, a separate search or examination of the prior art, which would unduly burden the Examiner, would not be required.

The Examiner also asserts that restriction is deemed proper between Invention IV and Invention V because their methods appear to constitute patentably distinct inventions, each with a distinct purpose and further comprising distinct methodologies and using different products.

Applicant respectfully disagrees, in that the method of Invention IV and the method of Invention V are closely related because they use similar methodologies and require similar materials. Applicant further submits that a reasonable search or examination of the prior art on the subject matter of either method would produce results related to both the methods utilizing the non-human transgenic animals comprising disruptions in TSH-R genes, as well those which utilize cells comprising the same disruptions. Such a search would not put serious burden on the Examiner.

Finally, the Examiner asserts that the products of Inventions I, II, III, VI and VII and Inventions IV and V are patentably distinct because the inventions are allegedly not disclosed as capable of use together and have different modes of operation, different functions, or different effects. Applicant disagrees with the Examiner's conclusion. Applicant believes that a reasonable search of the prior art, *e.g.* a search based on TSH-R disruptions, would produce results related to the subject matter of each of the invention groups. A search and examination of the claims of each of these inventions can therefore be made without additional burden on the Examiner.

Although Applicant has provisionally elected Invention III (claims 5-6, 12-38 and 40) for the purposes of advancing prosecution of the present application, Applicant contends for the foregoing reasons that the requirement for restriction between Inventions I through VII is improper. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the requirement.

Respectfully submitted,

Date: July 2, 2003

Kelly L. Quast

Kelly L. Quast (Reg. No. 52,141)

Deltagen, Inc.
700 Bay Road
Redwood City, CA 94063
(650) 569-5100

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(to be used for all correspondence after initial filing)

Application Number	10/045,624
Filing Date	October 26, 2001
First Named Inventor	Keith D. Allen
Art Unit	1632
Examiner Name	Peter Paras Jr.
Attorney Docket Number	R-666

Total Number of Pages in This Submission

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Kelly L. Quast, Reg. No. 52,141
Signature	<i>Kelly L. Quast</i>
Date	July 2, 2003

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